08/31/2004 17:15 FAX 631 549 0404

## In the Claims:

Please add the following new claims 54 to 65 and amend claims 35, 36, 38, 41 to 44, 48, 49 and 51 to 53 as follows:

Claims 1 to 31 (canceled).

32(previously presented). A method of manufacturing a bloadhesive tablet for controlling testosterone blood level in a person for therapeutic purposes, said method comprising embedding testosterone and/or one or more testosterone ester, separately or together, in an organic polymer, optionally together with at least one auxiliary agent, by a spray-drying process, so as to form an amorphous active ingredient premix;

wherein said one or more testosterone ester comprises a respective carboxylic acid radical with from 1 to 20 carbon atoms.

33(previously presented). The method as defined in claim 32, wherein said respective carboxylic acid radical is linear, branched, alicyclic, saturated and/or unsaturated and said respective carboxylic acid radical has up to five double and/or triple bonds.

34(previously presented). The method as defined in claim 32, wherein said amorphous active ingredient premix comprises said testosterone and said one or more testosterone ester in a ratio of said testosterone to said one or more

testosterone ester of from 1:100 to 1:1.

35(currently amended). The method as defined in claim 34, wherein said ratio is from 1:10 to 1:1.5 1:5.

36(currently amended). The method as defined in claim 35, wherein A method of manufacturing a bioadhesive tablet for controlling testosterone blood level in a person for therapeutic purposes, said method comprising embedding testosterone and one or more testosterone ester in an organic polymer in a ratio of 1:10 to 1:1.5, optionally together with at least one auxiliary agent, by a spray-drying process, so as to form an amorphous active ingredient premix;

wherein said spray-drying process comprises spray-drying a solution of said organic polymer, said testosterone and and/or said one or more testosterone ester and optionally said at least one auxiliary agent ingredient in a solvent; and

wherein said one or more testosterone ester comprises a respective carboxylic acid radical with from 1 to 20 carbon atoms.

37(previously presented). The method as defined in claim 36, wherein said solvent is ethanol and said organic polymer is polyvinyl pyrrolidone or hydroxypropylmethylcellulose.

38(currently amended). The method as defined in claim 32 or 36, further

→ US PTO

comprising mixing said amorphous active ingredient premix with at least one auxiliary ingredient to form a mixture and compressing said mixture to form said bioadhesive tablet.

39(previously presented). The method as defined in claim 32, further comprising mixing said amorphous active ingredient premix with at least one auxiliary ingredient to form an active ingredient layer mixture, preparing an adhesive layer mixture and compressing the active ingredient layer mixture together with the adhesive layer mixture to form said bioadhesive tablet with a bi-layer structure.

40(previously presented). The method as defined in claim 39, wherein said at least one auxiliary ingredient is selected from the group consisting of binders, fillers, lubricants, surfactants and a disintegration accelerator and said adhesive layer mixture comprises a bioadhesive polymer.

41(currently amended). The method as defined in claim 32 or 36, further comprising mixing said amorphous active ingredient premix with at least one auxiliary ingredient to form an active ingredient layer mixture, preparing at least one other layer mixture including an adhesive layer mixture and compressing the active ingredient layer mixture together with the at least one other layer mixture to form said bioadhesive tablet with a multi-layer structure.

42(currently amended). The method as defined in claim 32 or 36, wherein said

one or more testosterone ester has an ester group, said one or more testosterone ester is selected according to chain length and steric structure of said ester group, and wherein respective dosages of said testosterone and said one or more testosterone ester in said bioadhesive tablet are selected, so that a predetermined testosterone blood level <u>pattern in said person</u> is provided when said bioadhesive tablet is administered to said person.

43(currently amended). The method as defined in claim 32 or 36, wherein said one or more testosterone ester is selected from the group consisting of testosterone acetate, testosterone propionate, testosterone enantate, testosterone cipionate, testosterone cyclohexanecarboxylate, testosterone undecanoate undecenoate and testosterone bucyclate, so that said testosterone blood level in said person varies according to an endogenous circadian body rhythm when said bloadhesive tablet is administered to said person.

44(currently amended). The method as defined in claim 32 or 36, wherein said one or more testosterone ester includes testosterone <u>undecanoate</u> undecenate and wherein said testosterone and said testosterone <u>undecanoate</u> are embedded together in said organic polymer, in order to provide an extended time-release half-life.

45(previously presented). A bioadhesive tablet for controlling testosterone blood level in a person for therapeutic purposes, said bioadhesive tablet being made by

a method comprising embedding testosterone and/or one or more testosterone ester, separately or together, in an organic polymer, optionally together with at least one auxiliary agent, by a spray-drying process, so as to form an amorphous active ingredient premix;

wherein said one or more testosterone ester comprises a respective carboxylic acid radical with from 1 to 20 carbon atoms.

46(previously presented). The tablet as defined in claim 45, wherein said respective carboxylic acid radical is linear, branched, alicyclic, saturated and/or unsaturated and said respective carboxylic acid radical has up to five double and/or triple bonds.

47(previously presented). The tablet as defined in claim 45, wherein said amorphous active ingredient premix comprises said testosterone and said one or more testosterone ester in a ratio of said testosterone to said one or more testosterone ester of from 1:100 to 1:1.

48(currently amended). The tablet as defined in claim 47, wherein said ratio is from 1:10 to 1:1.5-1:5.

49(currently amended). The tablet as defined in claim 47, wherein A bioadhesive tablet for controlling testosterone blood level in a person for therapeutic purposes, said bioadhesive tablet being made by a method comprising

embedding testosterone and one or more testosterone ester in a ratio of 1:10 to 1: 1.5 in an organic polymer, optionally together with at least one auxiliary agent, by a spray-drying process, so as to form an amorphous active ingredient premix;

wherein said spray-drying process comprises spray-drying a solution of said organic polymer, said testosterone and and/or said one or more testosterone ester and optionally said at least one auxiliary agent ingredient in a solvent; and

wherein said one or more testosterone ester comprises a respective carboxylic acid radical with from 1 to 20 carbon atoms.

50(previously presented). The tablet as defined in claim 49, wherein said solvent is ethanol and said organic polymer is polyvinyl pyrrolidone or hydroxypropylmethylcellulose.

51(currently amended). The tablet as defined in claim 45 or 49, wherein said method comprises mixing said amorphous active ingredient premix with at least one auxiliary ingredient to form a mixture and compressing said mixture to form said bioadhesive tablet.

52(currently amended). The tablet as defined in claim 45 or 49, wherein said method comprises mixing said amorphous active ingredient premix with at least one auxiliary ingredient to form an active ingredient layer mixture, preparing an adhesive layer mixture and compressing the active ingredient layer mixture

Ø 009

together with the adhesive layer mixture to form said bioadhesive tablet with a bi-layer structure.

53(currently amended). The tablet as defined in claim 45 or 49, wherein said method comprises mixing said amorphous active ingredient premix with at least one auxiliary ingredient to form an active ingredient layer mixture, preparing at least one other layer mixture including an adhesive layer mixture and compressing the active ingredient layer mixture together with the at least one other layer mixture to form said bioadhesive tablet with a multi-layer structure.

54(new). The method as defined in claim 32, wherein said amorphous active ingredient premix comprises said one or more testosterone ester.

55(new). The method as defined in claim 54, wherein said one or more testosterone ester comprises testosterone undecanoate.

56(new). The method as defined in claim 54, wherein said spray-drying process comprises spray-drying a solution of said organic polymer, said one or more testosterone ester and optionally said at least one auxiliary agent in a solvent.

57(new). The method as defined in claim 56, wherein said solvent is ethanol.

58(new). The method as defined in claim 56, wherein said organic polymer is

selected from the group consisting of polyvinyl pyrrolidone, cellulose ethers and polyethylene glycols.

59(new). The method as defined in claim 56, further comprising mixing said amorphous active ingredient premix with at least one auxiliary ingredient to form a mixture and compressing said mixture to form said bloadhesive tablet and wherein said at least one auxiliary ingredient comprises a filler, a lubricant, a bloadhesive polymer, a surfactant and/or a disintegration accelerators.

60(new). The tablet as defined in claim 45, wherein said amorphous active ingredient premix comprises said one or more testosterone ester.

61(new). The tablet as defined in claim 60, wherein said one or more testosterone ester comprises testosterone undecanoate.

62(new). The tablet as defined in claim 60, wherein said spray-drying process comprises spray-drying a solution of said organic polymer, said one or more testosterone ester and optionally said at least one auxiliary agent in a solvent.

63(new). The tablet as defined in claim 62, wherein said solvent is ethanol.

64(new). The tablet as defined in claim 62, wherein said organic polymer is selected from the group consisting of polyvinyl pyrrolidone, cellulose ethers and

polyethylene glycols.

65(new). The tablet as defined in claim 62, further comprising mixing said amorphous active ingredient premix with at least one auxillary ingredient to form a mixture and compressing said mixture to form said bloadhesive tablet and wherein said at least one auxiliary ingredient comprises a filler, a lubricant, a bloadhesive polymer, a surfactant and/or a disIntegration accelerators.